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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,950	10/19/2001	Joshua Levy	HEMAC:58774	4919
24201	7590	03/30/2004	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 03/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 041,950

Applicant(s) LEVY et al

Examiner SAUNDERS

Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/2/04
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-38 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-38 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Amendment of 1/2/04 has been entered. Claims 1-38 are pending and under examination.

The following 112 issues remain or have been raised by entry of the amendment.

Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 38, penultimate line of each, "the collected concentrated..." lacks antecedent basis, since nothing has been recited as being "collected." Like considerations apply to recitations of "the collected..." in claims 36-37.

In claim 5 "the suspension" lacks antecedent basis. Applicant may recite, instead,--the step of suspending--.

Claim 11 is indefinite by failing to state what the addition of 4M sodium acetate accomplishes. Applicant must insert language that appears at the conclusion of claim 10.

In claim 17, line 2 "preferably" is indefinite.

In claim 20 "the protein solution" lacks any antecedent.

In claims 20-21, line 2 of each, it is considered that applicant does not intend to recite "solution". It is believed that applicant is intending to limit the "concentrating" step commencing at line 16 of claim 1.

In claim 23 it is not clear what act performs the solvent exchange step of claim 1. It is suggested that applicant recite claim 23 in a manner parallel to claim 22 by reciting

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--using a solution of sodium phosphate prepared by mixing--in lieu of "by preparing a mixture of."

In claim 25, line 2 "the protein solution" lacks antecedent basis; at line 3 "a new protein solution" requires replacement with terms recited in line 1.

Claim 30, line 3 "packed column" is unclear. Is this the anion-exchange or the c-18 column of claim 1?

In claim 31, lines 1-2, "purified" is recited twice.

In claim 32 "the concentrated protein solution" lacks antecedent basis.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step of adjusting the pH of the suspension to about 6.7 to 6.8 followed by a step of incubating.

Since these steps, which must appear after the "suspending step" are included in Fig. 1, in the description in the specification (pages 2 and 4), and in original claim 1, it must be assumed that these steps were essential to the invention.

Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 20-21, recite new matter by virtue of reciting a step of concentrating "the extract solution containing immune globulins"

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(examiner understands this to be what is obtained after “performing solvent exchange”) by ultrafiltration.

The ultrafiltration step was disclosed as occurring before, not after, the solvent exchange step. Applicant could overcome by deleting “solution” in line 2.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 38 recites new matter by virtue of not reciting all steps and limitations of the original disclosure.

In the “suspending” step at lines 4-5, applicant has failed to recite the required temperature range of - 4 to -6 degrees C. Figure 1, pages 2 and 4, and original claim 1 all recited a temperature within this range, or the range per se.

After line 5 applicant has failed to recite a step of “adjusting the pH of the suspension to about 6.7 to 6.8” as in original claim 1. The examiner also notes that Fig.1 recites “pH 5.70-5.80” at this point in the flow-chart. The examiner finds that page 2, line 9 recites “between 5.7 and 5.8” and that page 4, line 5 recites “pH 6.7 to 6.8” (the examiner has no idea whether “5.7 to 5.8” or “6.7 to 6.8” is correct; consistency is required). In any event, failing to stipulate the pH range introduces new matter.

In like manner claim 38 introduces new matter by failing to next recite an incubating step. See Fig. 1 reciting “Incubate 2 hours.” See page 2, line 1, reciting “incubated.” Note page 4, line 5 referring to Fig. 1. See original claim 1, line 7.

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By failing to recite all the steps/limitations of the method originally disclosed in its broadest context, applicant has improperly broadened the scope of invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Following the "suspending" step, additional steps of -- adjusting the pH of the suspension to about 6.7 to 6.8--followed by a step of -- incubating--are critical or essential to the practice of the invention, but not included in the claim(s). Claim 38 thus is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Since applicant did not disclose a method without these steps (Fig. 1, pages 2 and 4, and original claim 1) it must be assumed that these were essential to the invention.

Claims remain allowable over prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

March 29, 2004



DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~/644